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Felicia B. Satchell  
Director  
Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD, 20740-3835

24<sup>th</sup> July 2002

Dear Felicia Satchell,

**Re: Premarket Notification for a New Dietary Ingredient**

Further to my telephone conversation with Rhonda Kane and Ms. Kane's subsequent email of July 18<sup>th</sup> 2002, I would like to submit the following amendments to Pharmax's Premarket Notification for Echium Oil.

I would like to confirm that the notification that was written on June 17<sup>th</sup> 2002 is a total replacement of the initial notification that was written on May 7<sup>th</sup> 2002.

1. The Latin Binomial name of the source plant of echium oil is *Echium plantagineum* L. The author responsible for the correct scientific classification of the botanical is Linnaeus.
2. I am withdrawing the certificates written in German (pages 2-8 of Appendix 6 submitted on June 17<sup>th</sup> 2002) from the notification. The enclosed appendix is a complete replacement of the Appendix submitted on June 17<sup>th</sup> 2002.
3. The enclosed appendix includes a legible translation of each certificate of analysis. I have also enclosed legible copies of the following three articles that were not legible in the notification submitted on June 17<sup>th</sup> 2002.

Alexander, JW (1998). Immunonutrition : The Role of w-3 Fatty Acids. *Nutrition* 14 (7/8): 627-633.

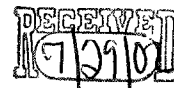
Culvenor CCJ (1956) The alkaloids of *Echium plantagineum* L. I. Echiumine and echimidine *Australian Journal Chemical* 9 512

Simopoulos AP (1991) Omega-3 fatty acids in health and disease and in growth and development *American Journal of Clinical Nutrition* 54 438

I would like to clarify that each bottle of echium oil will contain 300ml of the echium oil.

My contact details are:

Telephone: 0044 1792 472110  
Facsimile: 0044 1792 472466  
Email: [cathryn.cultech@btinternet.com](mailto:cathryn.cultech@btinternet.com)





In compliance with Dietary Supplement Health and Education Act of 1994 and in accordance with 21 CFR 190.6, Pharmax LLC hereby makes amendments to its official Premarket Notification for a new dietary ingredient, Echium oil. Accordingly, please find five (5) copies of these amendments enclosed.

Please be advised as follows:

1. The name and address of the distributor of the dietary supplement that contains a new dietary ingredient:

**Pharmax LLC  
120th Avenue NE,  
Bellevue  
WA 980005**

2. The name of the new dietary ingredient that is the subject of the premarket notification:

***Echium plantagineum* Seed Oil**  
**Latin Binomial name of the source plant :** ***Echium plantagineum* L.**  
**Botanical author:** **Linnaeus**

3. A description of the dietary supplement or dietary supplements that contain the new dietary ingredient:

- 1) Soft gel gelatine capsule 1000mg Echium oil.**  
**2) 300ml of liquid fatty acid nutritional supplement containing Echium Oil (in each bottle)**

- i) the level of the new dietary ingredient is:

- 1) 1000mg Echium oil per capsule**  
**2) 300ml of Echium oil per bottle**

- ii) the conditions of use recommended or suggested in the labelling of the dietary supplement:

- Suggested Use:**  
**1) One (1) or two (2) capsules to be taken daily as a dietary supplement, preferably at mealtimes, or as directed by a healthcare provider.**  
**2) 5ml of oil to be taken per day**

4. The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labelling of the dietary supplement, will be reasonably be expected to be safe:

**See Safety Evaluation of Echium Oil (Section 6 of Premarket Notification)**

Please find evidence within the notification that establishes that the dietary ingredient, Echium Oil, will reasonably be expected to be safe when used under the conditions suggested on the label. This documentation includes Certificates of Analysis, Product Specification Sheets and a safety evaluation of Echium oil.



Please could you confirm receipt of this amendment via email or fax.

Thank you for your time and attention to this matter. If you have any questions or comments, please do not hesitate to contact the undersigned.

Yours sincerely,

**Pharmax LLC**

**Cathryn E Wood**  
**Technical Scientist**

**[cathryn.cultech@btinternet.com](mailto:cathryn.cultech@btinternet.com)**

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**SA12 7BZ**  
**United Kingdom**

## **6.9 References (legible copies)**

Alexander, JW (1998). Immunonutrition : The Role of w-3 Fatty Acids. *Nutrition* **14** (7/8): 627-633.

Culvenor CCJ (1956) The alkaloids of *Echium plantagineum* L. I. Echiumine and echimidine *Australian Journal Chemical* **9** 512

Simopoulus AP (1991) Omega-3 fatty acids in health and disease and in growth and development *American Journal of Clinical Nutrition* **54** 438

***Boraginaceae* Echium plantagineum Linn.**  
Mant. ii. 202.

**Original Data**

Notes: Reg. Mediterr

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2 records found in the Index Nominum Genericorum database.  
Return to the search form. — View the help file.

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**[C] Echium** Linnaeus, Sp. Pl. 139. 1 Mai 1753.

LT.: *E. italicum* Linnaeus (vide N. L. Britton et A. Brown, Ill. Fl. N.U.S. ed. 2. 3: 93. 7 Jun. 1913)

PHAN.-BORAGINACEAE (59) 9 Feb 1996

**Isoplesion** Rafinesque, Fl. Tell. 4: 86. med. 1838 ('1836').

≡ *Echium* Linnaeus 1753

PHAN.-BORAGINACEAE (59) 9 Feb 1996

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## NCU-3e. Names in current use for extant plant genera

### Electronic version 1.0

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#### Entry for *Echium* L.

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- Citation: *Echium* L., Sp. Pl.: 139
  - Date: 1 Mai 1753
  - Type: *E. italicum* L.
  - Group: DICOTYLEDONES: BORAGINACEAE
- 

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Missouri Botanical Garden - w<sup>3</sup>TROPICOS

Nomenclatural Data Base - 22 Jul 2002

***Echium plantagineum* L.**

Family - BORAGINACEAE - Borage Family

**Published in:**

*Mantissa Plantarum* 2: 202. 1771.

{*Mant. Pl.*}

5 Synonym citation(s) for this name

13 Publication(s) citing this name

1 Homonymic or infraspecific name(s)

2 Chromosome count(s)

Link to NYBG specimen data base for this species

TROPICOS # 04001277



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## ***Echium plantagineum* L.**

Taxonomic Serial No.: 31898

### **Taxonomy and Nomenclature**

Kingdom:	Plantae
Taxonomic Rank:	Species
Synonym(s):	<i>Echium lycopsis</i> L. p.p.
Common Name(s):	salvation jane

<b>Taxonomic Status:</b>	
Current Standing:	accepted
Taxonomic Credibility	verified
Rating:	

### **Taxonomic Hierarchy**

Kingdom	Plantae
Subkingdom	Tracheobionta
Division	Magnoliophyta -- angiosperms, flowering plants
Class	Magnoliopsida -- dicotyledons
Subclass	Asteridae
Order	Lamiales
Family	Boraginaceae -- borage
Genus	<i>Echium</i> L. -- echium, vipersbugloss
Species	<i>Echium plantagineum</i> L. -- salvation jane

### **References**

<b>Expert(s):</b>	
Expert:	John Kartesz
Notes:	Biota of North America Project (BONAP)
Reference for:	

<b>Other Source(s):</b>	
Source:	Plants, Database (version 4.0.4)
Acquired:	1996
Notes:	
Reference for:	

Source:	Plants, database (version 5.1.1)
Acquired:	2000
Notes:	plants.usda.gov
Reference for:	

<b>Publication(s):</b>	
Author(s)/Editor(s):	
Publication Date:	
Article/Chapter Title:	
Journal/Book Name, Vol	
No..	
Page(s):	
Publisher:	
Publication Place:	
ISBN/ISSN:	
Notes:	
Reference for:	

## Geographic Information

**Geographic Division:** North America

**Jurisdiction/Origin:** Continental US, Introduced

## Comments

**Comment:**

Date Gene  
Wed Jul 24 2002 05 01 C

## Taxon: *Echium plantagineum* L.

**Genus:** *Echium*

**Family:** *Boraginaceae*.

**Nomen number:** 14875.

**Place of publication:** Mant. pl. 2:202. 1771.

**Name verified on:** 02-May-1995 by Systematic Botany Laboratory. **Last updated:** 17-Oct-2001.

**Species priority site is:** Western Regional PI Station (W6). 2 accessions (by country).

### Common names:

- **blueweed** (Source [Noxweed Aust](#))
- **Paterson's-curse** (Source [Econ PI Aust](#))
- **purple echium** (Source [Noxweed Aust](#))
- **purple viper's-bugloss** (Source [1 BritStace](#))
- **purple-bugloss** (Source [Noxweed Aust](#))
- **Riverina bluebell** (Source [Noxweed Aust](#))
- **Salvation Jane** (Source [Noxweed Aust](#))
- **viper's-bugloss** (Source [Noxweed Aust](#))

### Economic importance:

- **Bee plants** (fide CSIRO HEcPAus)
- **Environmental: ornamental** (fide [Diet Gard](#), [F Pak](#))
- **Vertebrate poisons: mammals** (fide [Cooper & Johnson](#), as *E. lycopsis*. [F verisi](#), as *E. lycopsis*. Kingsbury et al 1964, as *E. lycopsis*, [Lampe & McCann](#), as *E. lycopsis*)
- **Weed: potential seed contaminant** (fide [Noxweed Aust](#))

### Distributional range:

#### Native:

- **Africa:** Algeria [n ]; Egypt; Libya [n ]; Morocco; Portugal - Azores, Madeira Islands; Spain - Canary Islands; Tunisia
- **Asia-Temperate:** Cyprus; Georgia; Israel; Jordan; Lebanon; Syria; Turkey
- **Europe:** Albania; Bulgaria; France [incl Corsica]; Greece [incl Crete]; Italy [incl Sardinia, Sicily]; Portugal; Spain [incl Balears]; Ukraine - Krym; United Kingdom; Yugoslavia

#### Other:

- naturalized elsewhere

## References:

- Ali, S. I. & S. M. H. Jafri, eds. 1976-. Flora of Libya. (F Libya)
- Bramwell, D. 1972. Lagascalia 2:64.
- Cufodontis, G. 1953-1972. Enumeratio plantarum aethiopiae: Spermatophyta. (F EthiopCuf)
- Davis, P. H., ed. 1965-1988. Flora of Turkey and the east Aegean islands. (F Turk)
- Encke, F. et al. 1984. Zander: Handwörterbuch der Pflanzennamen, ed. 13. (Zander ed13)
- Greuter, W. et al., eds. 1984-. Med-Checklist. (L Medit)
- Hansen, A. & P. Sunding. 1993. Flora of Macaronesia: checklist of vascular plants, ed. 4. Sommerfeltia vol. 17. (L Macar ed4)
- Holm, L. et al. 1979. A geographical atlas of world weeds. (Atlas WWeed)
- Huxley, A., ed. 1992. The new Royal Horticultural Society dictionary of gardening. (Dict Gard)
- International Seed Testing Association. 1988. International Seed Testing: Association list of stabilized plant names. (ISTA)
- Komarov, V. L. et al., eds. 1934-1964. Flora SSSR. (F USSR)
- Lazarides, M. & B. Hince. 1993. CSIRO Handbook of Economic Plants of Australia. (Econ Pl Aust)
- Lems, K. 1960. Floristic botany of the Canary islands. (L Canar)
- Munz, P. A. & D. D. Keck. 1959. A California flora. (F CalifMunz)
- Nasir, E. & S. I. Ali, eds. 1970-. Flora of [West] Pakistan. (F Pak)
- Parsons, W. T. & E. G. Cuthbertson. 1992. Noxious weeds of Australia. (Noxweed Aust)
- Pignatti, S. 1982. Flora d'Italia. (F Ital)
- Quézel, P. & S. Santa. 1962-1963. Nouvelle flore de l'Algerie. (F Alger)
- Stace, C. 1995. New flora of the British Isles. (F BritStace)
- Täckholm, V. 1974. Students' flora of Egypt, ed. 2. (SF Egypt)
- Tutin, T. G. et al., eds. 1964-1980. Flora europaea. (F Eur)
- Wiersema, J. H. & B. León. 1999. World economic plants: a standard reference. (World Econ Pl)

## Synonyms:

- Echium lycopsis auct.
- Echium violaceum auct.  
(previously associated with 1 accession)

## Check other databases for *Echium plantagineum*:

- Flora Europaea: Database of European Plants (ESFEDS)

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| [USDA](#) | [ARS](#) | [GRIN](#) | [NPGS](#) | [New Search](#) |

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Cite as: USDA, ARS, National Genetic Resources Program. *Germplasm Resources Information Network - (GRIN)*. [Online Database] National Germplasm Resources Laboratory, Beltsville, Maryland. Available: [http://www.ars-grin.gov/var/apache/cgi-bin/npgs/html/tax\\_search.pl?echium+plantagineum](http://www.ars-grin.gov/var/apache/cgi-bin/npgs/html/tax_search.pl?echium+plantagineum) (04 July 2002)

Send your comments to: [Dr. J. H. Wiersema](#).

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